

REMARKS

This Amendment and Response (the "Amendment") is submitted in response to the non-final Office Action dated April 25, 2008 (the "Office Action").

Initially, it should be noted that there is a discrepancy between page 1 of the Office Action, which indicates that the Office Action is non-final, and paragraph 15 of the Office Action, which indicates that the Office Action is a final action. Applicants' attorneys confirmed with Examiner Ganesan on May 20, 2008 that the Office Action is non-final.

I. STATUS OF THE CLAIMS

Following entry of this Amendment, claims 111-170 remain pending in the application. Claims 111-138 are in independent form.

By this Amendment, as outlined above, Applicants amend claims 111-138. More specifically, claims 111-138 have been amended to recite that at least a portion of the undercoat covers at least a portion of the metallic or stainless steel stent portion and that the topcoat at least partially covers the portion of the undercoat that covers at least a portion of the metallic or stainless steel stent portion. In addition, claim 113 has been amended to include recitations that were inadvertently omitted from claim 113 as set forth in the Amendment dated March 17, 2008. Lastly, claims 129-138 have been amended to include the term "copolymer" between the terms "acetate" and "material."

All amendments are fully supported by the originally-filed specification and/or drawings of the present application. For instance, the amendments are supported by the specification at, *inter alia*, page 7, lines 33-35 and page 23, lines 23-33. It is believed that no new matter has been added. Applicants expressly reserve the right to pursue the subject matter of any previously presented claims in one or more continuation applications.

II. TELEPHONE INTERVIEW SUMMARY

Examiner Ganesan is thanked for granting Applicants' attorneys a telephone interview on April 1, 2008. Participants in the interview included Examiner Suba Ganesan, and Applicants' attorneys Cathy Chin Eng and Anthony D. Mustillo. The Office Action mailed on November 19, 2007 and the references cited therein were discussed. Specifically, Applicants' attorneys pointed out that U.S. Patent No. 5,464,650 to Berg *et al.* ("Berg") fails to disclose or suggest a coating that includes a topcoat that is substantially free of an elutable material or a topcoat comprising a biostable polymeric material that is different from the

hydrophobic elastomeric material or ethylene vinyl acetate copolymer material of the undercoat as recited in the amended claims submitted on March 17, 2008. In response, Examiner Ganesan agreed to reconsider the rejections based on Berg.

In addition, Examiner Ganesan noted that the version of claim 113 submitted on March 17, 2008 appeared to be missing some recitations that were previously included in claim 113. Applicants representatives agreed to review the claim stating that any recitations that were not included may have been inadvertently omitted.

III. THE CLAIM REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

In paragraph 3 of the Office Action, claim 113 is rejected under 35 U.S.C. § 112, second paragraph ("Section 112") as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. It appears that two lines of the claim were inadvertently omitted from the claim in the previous response that was filed on March 17, 2008. Accordingly, the omitted lines have been added to claim 113.

Further, paragraph 4 of the Office Action states that there is insufficient antecedent basis for the "ethylene vinyl acetate copolymer material" recitation in claims 129-138. In response, as outlined above, claims 129-138 have been amended.

Accordingly, Applicants respectfully request that the Section 112 rejections be withdrawn.

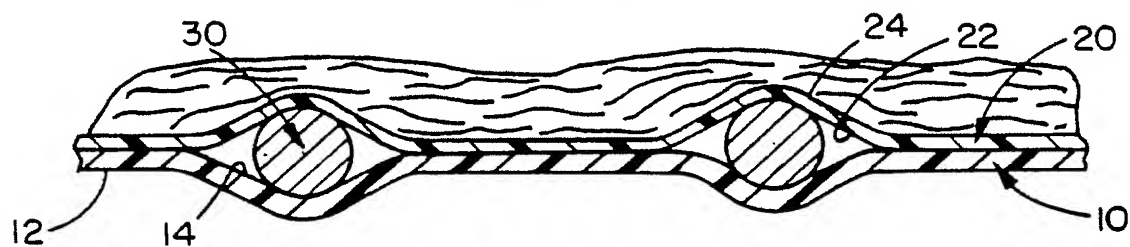
IV. THE CLAIM REJECTIONS UNDER 35 U.S.C. § 102(b)

In paragraph 6 of the Office Action, claims 111, 124, 125, 139-141, 154, 155, 169 and 170 are rejected under 35 U.S.C. § 102(b) ("Section 102(b)") as allegedly being anticipated by U.S. Patent No. 5,123,917 to Lee (hereinafter "Lee"). The rejection is traversed for at least the following reasons.

Independent claims 111, 124 and 125 are directed to stents having at least a portion that is implantable into the body of a patient, wherein at least a part of the stent portion is metallic and wherein at least part of the metallic stent portion is covered with a coating for release of a biologically active material. The coating comprises an undercoat comprising a first polymer and a topcoat comprising a second polymer that is different from the first polymer. At least a portion of the undercoat covers at least a portion of the metallic stent portion and the topcoat at least partially covers the portion of the undercoat that covers at least a portion of the metallic stent portion. Applicants respectfully submit that Lee fails to disclose stents having such a coating.

In particular, in paragraph 7 of the Office Action, the Examiner equates the inner layer 10, outer layer 20 and scaffold members 30 in Lee, to the undercoat, topcoat and metallic stent, respectively, of the presently-claimed device. In contrast to the presently-claimed device, however, Lee teaches that the scaffold members 30 are “[p]ositioned *between* the inner layer 10 and the outer layer 20.” (Lee, col. 5, lines 16-17; *see also* col. 2, lines 34-42; col. 3, lines 58-63) (emphasis added). Figure 4 of Lee, which is reproduced below, shows that the scaffold members 30 are disposed between the inner layer 10 and the outer layer 20.

FIG. 4



Thus, in Lee's device, the outer layer 20 is not disposed on a portion of the inner layer 10 that covers a part of the scaffold member 30. Therefore, Lee fails to disclose a stent having a coating comprising an undercoat, which comprises a first polymer, and a topcoat, which comprises a polymer different from the first polymer, wherein “at least a portion of the undercoat covers at least a portion of the metallic stent portion” and wherein the topcoat “at least partially covers the portion of the undercoat that covers at least a portion of the metallic stent portion.”

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *M.P.E.P.* § 2131 (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed Cir. 1987)). Accordingly, because Lee fails to disclose each and every element set forth in the claims, the Section 102(b) rejections must fail as a matter of law. Therefore, Applicants respectfully submit that independent claims 111, 124 and 125 and their dependent claims, 139-141, 154, 155, 169 and 170, are not anticipated by Lee and request that the Section 102 rejections be withdrawn.

V. THE REJECTIONS UNDER 35 U.S.C. § 103(a)

In paragraph 9 of the Office Action, claims 112, 113, 129, 130, 142, 143, 159 and 160 are rejected under 35 U.S.C § 103(a) (“Section 103(a)”) as allegedly being unpatentable over Lee in view of U.S. Patent No. 5,464,650 to Berg *et al.* (hereinafter “Berg”). In addition, in paragraph 11 of the Office Action, claims 114-116, 118-121, 128, 131-138, 144-146, 148-151, 158 and 161-168 are rejected under Section 103(a) as allegedly being unpatentable over Lee in view of Berg, and further in view of U.S. Patent No. 5,288,711 to Mitchell *et al.* (hereinafter “Mitchell”). Lastly, in paragraph 13 of the Office Action, claims 117, 122, 123, 126, 127, 147, 152, 153, 156 and 157 are rejected under Section 103(a) as allegedly being unpatentable over Lee in view of Mitchell. The rejections are traversed for at least the following reasons.

A. The Legal Standard

A finding of obviousness requires that “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103(a).

In its recent decision addressing the issue of obviousness, *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), the Supreme Court stated that the following factors set forth in *Graham v. John Deere Co.*, 383 U.S. 1, (1966) still control an obviousness inquiry: (1) the scope and content of the prior art; (2) the differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *KSR*, 127 S. Ct. at 1734 (*quoting Graham*, 383 U.S. at 17-18).

The Supreme Court rejected a rigid application of the “teaching, suggestion, or motivation” test previously applied by the Court of Appeals for the Federal Circuit. *KSR*, 127 S. Ct. at 1739. The Supreme Court, however, affirmed that it is “important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does . . . because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *Id.* at 127 S. Ct. at 1741. Thus, consistent with the principles enunciated in *KSR*, a *prima facie* case of obviousness can be established by showing a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the

art, to modify the reference *and* to carry out the modification with a reasonable expectation of success, viewed in light of the prior art. The suggestion and the reasonable expectation of success must both be found in the prior art and must *not* be based on the applicant's disclosure. *In re Dow Chemical Co.*, 837 F.2d 469 (Fed. Cir. 1988).

Accordingly, when an obviousness rejection is based on a combination of elements individually found in the prior art, the M.P.E.P. specifies that after resolution of the Graham factual inquiries, Office personnel must articulate all of the following to support a conclusion of obviousness:

- (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;
- (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely performs the same function as it does separately;
- (3) a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

M.P.E.P. § 2143(A) (citing *KSR*, 550 U.S. at ____; *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282 (1976); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63 (1969); *Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, (1950)). Accordingly, each claim element must be found in the prior art.

B. The Claims Are Patentable Over Lee in View of Berg

In paragraph 9 of the Office Action, claims 112, 113, 129, 130, 142, 143, 159 and 160 are rejected under Section 103(a), as allegedly being unpatentable over Lee in view of Berg. The rejection is traversed for at least the following reasons.

Independent claims 112, 113, 129 and 130 are directed to stents having at least a portion that is implantable into the body of a patient, wherein at least a part of the stent portion is stainless steel covered with a coating for release of a biologically active material.

The coating comprises an undercoat and a topcoat, wherein at least a portion of the undercoat covers at least a portion of the stainless steel portion and wherein the topcoat at least partially covers the portion of the undercoat that covers at least a portion of the stainless steel portion. These claims also recite that the undercoat comprises an ethylene vinyl acetate copolymer material incorporating an amount of a biologically active material, and a topcoat comprising a biostable polymeric material, which is different from the ethylene vinyl acetate copolymer material. Applicants respectfully submit that Lee and Berg, alone or in combination, fail to disclose or suggest stents having such a coating.

In paragraph 10 of the Office Action, the Examiner acknowledges that Lee fails to disclose an undercoat comprising an ethylene vinyl acetate copolymer material and cites Berg for teaching an ethylene vinyl acetate copolymer material. (*Office Action*, ¶ 10). As discussed above in Section IV, Lee fails to disclose a stent having a metallic portion and a coating comprising an undercoat, which comprises a first polymer, and a topcoat, which comprises a polymer different from the first polymer. Lee also fails to disclose that at least a portion of the undercoat covers at least a portion of the metallic stent portion and that the topcoat at least partially covers the portion of the undercoat that covers at least a portion of the metallic stent portion. Applicants respectfully submit that Berg fails to cure the deficiencies of Lee.

More specifically, Berg also fails to disclose a stent having a metallic portion and a coating covering at least a part of the metallic stent portion in which the coating comprises (a) an undercoat that comprises a first polymer and covers at least a portion of the metallic stent portion, and (b) a topcoat comprising a second polymer that is different from the first polymer of the undercoat and which at least partially covers the portion of the undercoat that covers at least a portion of the metallic stent portion. Instead, Berg discloses that compositions containing the same polymer are applied to its stent. Berg does not disclose or even suggest the use of a first coating composition comprising a first polymer and a second coating composition that comprises a second polymer that is different from the first polymer. Further, none of the stents prepared in Berg's examples include a plurality of layers having different polymers. Each example only discloses the use of a single polymer to form the coatings. (*See Berg*, col. 5, line 45 to col. 7, line 15).

For at least the foregoing reasons, it is believed that independent claims 112, 113, 129 and 130 are patentable over Lee and Berg, either taken alone or in combination. Further,

claim 142, which depends from claim 112, claim 143, which depends from claim 113, claim 159, which depends from claim 129 and claim 160, which depends from claim 130, are believed to be patentable as well. Accordingly, Applicants respectfully request that the rejection based on Lee and Berg be withdrawn.

C. The Claims Are Patentable Over Lee in view of Berg and Mitchell

In paragraph 11 of the Office Action, claims 114-116, 118-121, 128, 131-138, 144-146, 148-151, 158 and 161-168 are rejected under Section 103(a), as allegedly being unpatentable over Lee in view of Berg, and further in view of Mitchell. The rejections are traversed for at least the following reasons.

Independent claims 114-116, 118-121, 128 and 131-138 are directed to stents having at least a portion which is implantable into the body of a patient, wherein at least a part of the stent portion is either stainless steel or metallic and wherein the stainless steel or metallic portion is covered with a coating for release of a biologically active material. The coating comprises an undercoat, comprising a first polymer, and a topcoat, comprising a polymer different from the first polymer. At least a portion of the undercoat covers at least a portion of the stainless steel or metallic stent portion and where at least a portion of the topcoat at least partially covers the portion of the undercoat that covers at least a portion of the stainless steel or metallic stent portion. Applicants respectfully submit that Lee, Berg and Mitchell, alone or in combination, fail to disclose or suggest stents having such a coating.

In paragraph 12 of the Office Action, the Examiner asserts that Lee in view of Berg teaches the claimed coated stent but fails to teach a coating comprising an antibiotic. (*Office Action*, ¶ 12). For the reasons discussed above in Section IV and V(B), Applicants respectfully submit that Lee in combination with Berg fails to disclose or suggest the claimed stent. Additionally, Applicants submit that Mitchell fails to cure the deficiencies with Lee and Berg.

More specifically, Mitchell also fails to disclose a stent having a metallic portion and a coating covering at least a part of the metallic stent portion in which the coating comprises (a) an undercoat that comprises a first polymer and covers at least a portion of the metallic stent portion, and (b) a topcoat comprising a second polymer that is different from the first polymer of the undercoat and which at least partially covers the portion of the undercoat that covers at least a portion of the metallic stent portion. In fact, Mitchell never discloses or suggests a polymer coating being disposed on a stent, much less discloses or suggests a stent

having more than one coating (*i.e.*, an undercoat and a topcoat) having the particular properties recited in the claims.

For at least the foregoing reasons, it is believed that independent claims 114-116, 118-121, 128 and 131-138 are patentable over Lee, Berg and Mitchell, either taken alone or in combination. Further, claims 144-146, which depend from claims 114-116, respectively, claims 148-151, which depend from claims 118-121, respectively, claim 158, which depends from claim 128 and claims 161-168, which depend from claims 131-138, respectively, are believed to be patentable as well. Accordingly, Applicants respectfully request that the rejection based on Lee, Berg and Mitchell be withdrawn.

D. The Claims Are Patentable Over Lee in view of Mitchell

In paragraph 13 of the Office Action, claims 117, 122, 123, 126, 127, 147, 152, 153, 156 and 157 are rejected under Section 103(a), as allegedly being unpatentable over Lee in view of Mitchell. The rejection is traversed for at least the following reasons.

Independent claims 117, 122, 123, 126 and 127 are directed to stents having at least a portion that is implantable into the body of a patient, wherein at least a part of the stent portion is metallic and wherein at least a part of the metallic portion is covered with a coating for release of a biologically active material. The coating comprises an undercoat, comprising a first polymer, and a topcoat, comprising a polymer different from the first polymer. At least a portion of the undercoat covers at least a portion of the metallic stent portion, and wherein at least a portion of the topcoat at least partially covers the portion of the undercoat that covers at least a portion of the metallic stent portion. Applicants respectfully submit that Lee and Mitchell, alone or in combination, fail to disclose or suggest stents having such a coating.

In paragraph 14 of the Office Action, the Examiner asserts that Lee teaches the claimed stent but fails to teach a coating comprising an antibiotic and cites Mitchell for teaching a coating comprising an antibiotic. (*Office Action*, ¶14). For the reasons discussed above in Section IV and V(C), Applicants respectfully submit that Lee and Mitchell, either alone or in combination, fail to disclose or suggest the claimed stent.

For at least the foregoing reasons, it is believed that independent claims 117, 122, 123, 126 and 127 are patentable over Lee and Mitchell, either taken alone or in combination. Further, claim 147, which depends from claim 117, claim 152, which depends from claim 122, claim 153, which depends from claim 123, claim 156, which depends from claim 126

and claim 157, which depends from claim 127, are believed to be patentable as well. Accordingly, Applicants respectfully request that the rejection based on Lee and Mitchell be withdrawn.

CONCLUSION

In view of the above remarks, Applicants respectfully request that the Examiner reconsider pending claims 111-170 with a view towards allowance.

The Examiner is invited to call the undersigned attorney at (212) 326-3939 if a telephone call could help resolve any remaining issues.

Should any fees be required, please charge such fees to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

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